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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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10/817,172

04/02/2004

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Plantar Fasciitis

3082

7590
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08/04/2009

EXAMINER

PATEL, TARLA R

ART UNIT

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PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No. 10/817,172	Applicant(s) BUSHBY, DONALD P.	
	Examiner TARLA R. PATEL	Art Unit 3772	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 7/9/09.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 44-80 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 44-80 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____ |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Claim Objections

1. Claim 45 is objected to because of the following informalities: The claims do not end in a (.) and as a result it is unclear if there are more limitations or if the claim should end as they stand. Appropriate correction is required.

Claim Rejections - 35 USC § 112

2. The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

3. Claims 45, 47, 61, 67, 69, 72, 77, 78 and 79 rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. These claims 45, 47, 61, 67, 69, 72, 77, 78 and 79 recite limitations of a ratio of elongation to tensile strength is less than 0.9 and exhibits 15% elongation when subjected to a tensile load approximately equivalent to 25 pounds/inch are not clear to one having ordinary skill in art from the disclosure of originally filed specification that how applicant has concluded the specifics of these limitations, there are no examples to show the finding and what is elongation at different tensile load of for examples 2, 5, 10, 15, 20, 30, 35 and so on. The examiner can best understood by the claim recited limitations of approximately equivalent to 25 pounds/inch, that these finding are not clear. Further, with the limitations of ratio of elongation, how applicant is determined the ratio of elongation of less than 0.9, whether is it linear ratio? Was is determine up to tear or breaking point of

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material? How is it determined? There is no substantially data or examples to support the finding of these specific claim limitations.

Claim Rejections - 35 USC § 103

4. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

5. Claims 44, 55, 62, 66 and 70-71 are rejected under 35 U.S.C. 103(a) as being unpatentable over Burgess (6,640,465) in view of Holden (2004/0006814).

Burgess discloses an orthotic plantar fascia device for providing support to and reducing stress on, the plantar fascia of a human foot. The device comprises a thin, flexible and conformable lining; with respect to the limitation of "stretch resistant" Burgess' device (110) is both flexible and conformable to the foot. The device further includes an adhesive layer (120) on the sole engaging surface for adhering the device directly to the outer skin tissue on the sole of the foot (column 2 lines 62-67) and a protective cover (150) removably disposed over adhesive layer, that when removed, exposes the adhesive layer (column 4 lines 50-55). Also, Burgess discloses the liner will remain on the foot to allow mobility while still having increased adhesion as a greater effective contact surface area is provided (abstract). Applicant sets forth in the disclosure of the invention that the stretch resistant device" is a sufficiently flexible article with adhesive lining and that adhesive on the sole of the linings when the lining is on the surface of the

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foot imparts at least some restriction to extension and stretching of the tissue. The liner of Burgess when applied to the sole of the foot is applied with an adhesive and will provide a prevention and stretch of the tissue, therefore, Burgess's liner is equivalent to the claimed support's "stretch resistant" property, since there are no other distinguish structures is required to be stretch less, the device of Burgess meets this claimed limitation. The device has a sole engaging surface (see figure 2), sized and shaped to engage the outer skin tissue on the sole of the foot (column 2 lines 38-40) and extend along the plantar fascia region of the foot from about the ball of the foot to the heel of the foot for providing support to the plantar fascia region of the foot (see fig 2).

Burgess does not disclose that the foot protector can be formed into different sizes or cuts to fit by the wearer. However, Holden teaches a protective attachment that removably attaches to the bottom of the foot (abstract) that is easily trimmed to fit the size and shape of the body part [0003]. At the time of the invention was made, it would have been obvious design choice to one having ordinary skill in the art to form the device of Burgess into different sizes or cuts to fit by the wearer, as taught by Holden to fit various size of feet and to cover whole or partial as user desire.

With respect to claim limitations to a method for reducing stress on the plantar fascia of a human foot comprising the steps of providing a thin flexible device of uniform thickness having sole engaging surface and adhering sole engaging surface to the outer skin tissue on the sole of the foot to extend from the heel of the foot to at least the mid portion of the foot to provide support to the plantar fascia region, since Burgess

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discloses an equivalent structure shown to be “stretch-resistant device” as explained above, the Burgess device meets the claim limitation.

With respect to claim 55, Burgess obviously discloses a single woven fabric layer (as disclosed in column 4 lines 5-8 that the it is made of natural fibers, the examiner interprets that the natural fiber is woven fabric layer as required by claim), an adhesive layer (120) and a protective cover layer (150) remove ably disposed on said adhesive layer (see figure 8).

With respect to the limitations of “restricting extension and stretching of the outer skin tissue on the sole of the foot”, when the device described above adheres to sole, it will obviously restrict extension of the skin and such that the tension forces applied to the plantar fascia from the forces on an arch of the foot which push the bones of the foot downwardly, and are able to reduce tension in the plantar fascia (0027), when the device of Burgess is secured to the sole of the user’s foot which will result in treating pain in at least one of the heel, or arch or ball of the foot (see paragraph 0016 and 0027) and controls the step to prevent extension and stretching, reduce tension on the plantar fascia of the foot.

6. Claims 48-54 and 56-60, 62-66 are rejected under 35 U.S.C. 103(a) as being unpatentable over Burgess and Holden in view of Domenico (3,584,622).

Burgess substantially discloses an orthotic plantar fascia device for providing support to and reducing stress on, the plantar fascia of a human foot. The device comprises a thin,

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flexible and conformable lining; with respect to the limitation of "stretch resistant"

Burgess' device (110) is both flexible and conformable to the foot. The device further includes an adhesive layer (120) on the sole engaging surface for adhering the device directly to the outer skin tissue on the sole of the foot (column 2 lines 62-67) and a protective cover (150) removably disposed over adhesive layer, that when removed, exposes the adhesive layer (column 4 lines 50-55). Also, Burgess discloses the liner will remain on the foot to allow mobility while still having increased adhesion as a greater effective contact surface area is provided (abstract). Applicant sets forth in the disclosure of the invention that the stretch resistant device" is a sufficiently flexible article with adhesive lining and that adhesive on the sole of the linings when the lining is on the surface of the foot imparts at least some restriction to extension and stretching of the tissue. The liner of Burgess when applied to the sole of the foot is applied with an adhesive and will provide a prevention and stretch of the tissue, therefore, Burgess's liner is equivalent to the claimed support's "stretch resistant" property, since there are no other distinguish structures is required to be stretch less, the device of Burgess meets this claimed limitation. The device has a sole engaging surface (see figure 2), sized and shaped to engage the outer skin tissue on the sole of the foot (column 2 lines 38-40) and extend along the plantar fascia region of the foot from about the ball of the foot to the heel of the foot for providing support to the plantar fascia region of the foot (see fig 2).

However, Burgess and Holden does not discloses thin flexible straps extending laterally outward from opposite sides to at least partially encircle the talus, the navicular, the

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cuneiform and the cuboid region of the foot, an arch strap and a heel strap, wherein the straps can be adhered to the foot by an adhesive for securing the straps around the portions of the foot as required by claims 48,51,53,56,57,58,59,60, and 61 and With respect to claims 50,52 and 54, further, Burgess does not disclose the straps are integrally formed with device (see fig 1).

However, Domenico teaches a support device for prevention of ankle injuries comprising thin flexible straps extending laterally outward from opposite sides to at least partially encircle the talus, the navicular, the cuneiform and the cuboid region of the foot, an arch strap and a heel strap (26 as shown see figs 2 and 4), wherein the straps can be adhered to the foot by an adhesive (column 2 lines 51-54) for securing the straps around the portions of the foot (see figure 2 and 4 and column 2 lines 51-54) as required by claims 48,51,53,56,57,58,59, and 60, further, Domenico discloses the straps are integrally formed with device (see fig 2 and 4) as required by claims 50,52 and 54. At the time of the invention, it would have been obvious to one skilled in art to have to make the device of Burgess and Holden to have straps having adhesive, as taught by Domenico to have adhesive on top surface of the device to adhere the support device to the bottom of the foot and to secure the device better to sole of the foot.

With respect to claims 56, and 60, the limitations of “restricting extension and stretching of the outer skin tissue on the sole of the foot”, when the device described above adheres to sole, it will obviously restrict extension of the skin and such that the tension forces applied to the plantar fascia from the forces on an arch of the foot which push the

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bones of the foot downwardly, and are able to reduce tension in the plantar fascia (0027), when the device of Burgess is secured to the sole of the user's foot which will result in treating pain in at least one of the heel, or arch or ball of the foot (see paragraph 0016 and 0027) and controls the step to prevent extension and stretching, reduce tension on the plantar fascia of the foot.

7. Claims 45, 72, 75-76, 78 and 80 are rejected under 35 U.S.C. 103(a) as being unpatentable over Burgess and Holden in view of Desnoyers (3,482,683).

Burgess and Holden substantially disclose the invention as claimed; see rejection to claims 44, 55, 62, 66 and 70-71 above; further with the limitation of sole support does not including a resilient cushion layer, the examiner agrees that the Burgess discloses to have cushion effect (column 3 lines 16-20), however, it has been interpreted by the examiner that even bottom of foot sole have natural cushion in form of muscles, then how one claim limitation to not have cushion layer, since naturally human body is cushion at bottom of feet sole in form of muscles. However, Burgess and Holden does not disclose that the sole member has a ratio of elongation (%) to tensile strength (lb/in-width) that is less than 0.9, whereby providing a balanced combination of strength and resistance to elongation.

However, Desnoyers teaches a pressure sensitive tape having material having ratio of elongation to tensile strength ratio of at least about 3 to 1 (column 3 lines 18-26, as broadly interpreted as less than 0.9 because range of at least about in broadest term would meet required limitation). At the time of the invention was made, it would have

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been obvious to one having ordinary skill in the art to use the material to make the device of Burgess and Holden to have tensile strength to ratio of elongation, as taught by Desnoyers to have resistance to tearing.

8. Claim 46 is rejected under 35 U.S.C. 103(a) as being unpatentable over Burgess, Holden and Desnoyers.

Burgess, Holden and Desnoyers substantially disclose the invention as claimed; see rejection to claim 45 above, further, Burgess discloses a device that has a uniform thickness (column 3 lines 52-54) of less than about 30 mils, (since column 3 lines 13-15, describes the thickness of about 1 mm to about 5 mm inherently discloses the less than about 30 mils required by claim, since examiner interprets “about” language as broadest reasonable interpretation, since 1 mils= 0.0254 mm) and formed of a fabric material (column 4 lines 5-10) Burgess further discloses a protective layer (150). However, Burgess, Holden and Desnoyers do not disclose that device is specifically 30 mils (0.762 mm) in thickness. At the time of the invention was made, it would have been obvious design choice to one having ordinary skill in the art to have thickness of 30 mils, since, such a modification would have involved a mere change in the size of a component. A change in size is generally recognized as being within the level of ordinary skill in the art. *In re Rose*, 105 USPQ 237 (CCPA 1955).

9. Claims 47, 61, 67 and 69 are rejected under 35 U.S.C. 103(a) as being unpatentable over Burgess and Holden in view of Huddleston et al. (4,997,709).

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Burgess, and Holden substantially disclose the invention as claimed; see rejection to claims 44, 55, 62, 66 and 70-71 above, further, Burgess and Holden discloses a device that has a uniform thickness (column 3 lines 52-54) of less than about 30 mils, (since column 3 lines 13-15, describes the thickness of about 1 mm to about 5 mm inherently discloses the less than about 30 mils required by claim, since examiner interprets “about” language as broadest reasonable interpretation, since 1 mils= 0.0254 mm) and formed of a fabric material (column 4 lines 5-10) Burgess further discloses a protective layer (150). However, Burgess and Holden do not disclose that device is specifically 30 mils (0.762 mm) in thickness. At the time of the invention was made, it would have been obvious design choice to one having ordinary skill in the art to have thickness of 30 mils, since, such a modification would have involved a mere change in the size of a component. A change in size is generally recognized as being within the level of ordinary skill in the art. *In re Rose*, 105 USPQ 237 (CCPA 1955).

Burgess and Holden substantially disclose the invention as claimed; see rejection to claims 44, 55, 62, 66 and 70-71 above; Burgess and Holden does not disclose a support device that has less than 15% elongation when subjected to a tensile load (lb/in-width) approximately equivalent to 25 pounds/inch in accordance with ASTM D3759.

However, Huddleston et al. teaches novel adhesives and tapes having the tensile load (lb/in-width) approximately equivalent to 25 pounds/inch in accordance with ASTM D3759 (column 1 lines 48-63). At the time of the invention, it would have been an obvious to one skilled in art to modify the device of Burgess and Holden to include the

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adhesives of the tensile load (lb/in-width) approximately equivalent to 25 pounds/inch in accordance with ASTM D3759, as taught by Huddleston et al. to have more resiliencies to the device.

10. Claim 68 is rejected under 35 U.S.C. 103(a) as being unpatentable over Burgess, Holden and Huddleston et al.

Burgess, Holden and Huddleston et al substantially disclose the invention as claimed; see rejection to claim 61 above, further, Burgess obviously discloses a single woven fabric layer (as disclosed in column 4 lines 5-8 that the it is made of natural fibers, the examiner interprets that the natural fiber is woven fabric layer as required by claim), an adhesive layer (120) and a protective cover layer (150) remove ably disposed on said adhesive layer (see figure 8).

Burgess also discloses a device that has a uniform thickness (column 3 lines 52-54) of less than about 30 mils, (since column 3 lines 13-15, describes the thickness of about 1 mm to about 5 mm inherently discloses the less than about 30 mils required by claim, since examiner interprets "about" language as broadest reasonable interpretation, since 1 mils= 0.0254 mm) and formed of a fabric material (column 4 lines 5-10). However, Burgess, Holden and Huddleston et al does not discloses that device is 30 mils (0.762 mm) in thickness. At the time of the invention was made, it would have been obvious design choice to one having ordinary skill in the art to have thickness of 30 mils, since, such a modification would have involved a mere change in the size of a component. A

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change in size is generally recognized as being within the level of ordinary skill in the art. *In re Rose*, 105 USPQ 237 (CCPA 1955).

11. Claims 73-74 are rejected under 35 U.S.C. 103(a) as being unpatentable over Burgess, Holden and Desnoyers.

Burgess, Holden and Desnoyers substantially disclose the invention as claimed; see rejection to claim 72 above, further, Burgess obviously discloses a woven micro fiber layer (as disclosed in column 4 lines 5-8 that the it is made of synthetic fiber that is interpreted to be polyester since polyester is blend of fibers and by definition micro-fiber is a very fine polyester fiber, therefore the examiner interprets that the synthetic fiber meets the limitation of a woven micro-fiber layer as required by claim), an adhesive layer (120) and a protective cover layer (150) remove ably disposed on said adhesive layer (see figure 8).

Burgess also discloses a device that has a uniform thickness (column 3 lines 52-54) of less than about 30 mils, (since column 3 lines 13-15, describes the thickness of about 1 mm to about 5 mm inherently discloses the less than about 30 mils required by claim, since examiner interprets "about" language as broadest reasonable interpretation, since 1 mils= 0.0254 mm) and formed of a fabric material (column 4 lines 5-10). However, Burgess, Holden and Desnoyers does not discloses that device is 30 mils (0.762 mm) in thickness. At the time of the invention was made, it would have been obvious design choice to one having ordinary skill in the art to have thickness of 30 mils, since, such a modification would have involved a mere change in the size of a component. A change in size is generally recognized as being within the level of ordinary skill in the art. *In re*

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Rose, 105 USPQ 237 (CCPA 1955).

12. Claims 77 and 79 are rejected under 35 U.S.C. 103(a) as being unpatentable over Burgess, Holden and Desnoyers in view of Huddleston et al. (4,997,709).

Burgess, Holden and Desnoyers substantially disclose the invention as claimed; see rejection to claims 75 and 78 above; Burgess, Holden and Desnoyers do not disclose a support device that has less than 15% elongation when subjected to a tensile load (lb/in-width) approximately equivalent to 25 pounds/inch in accordance with ASTM D3759.

However, Huddleston et al. teaches novel adhesives and tapes having the tensile load (lb/in-width) approximately equivalent to 25 pounds/inch in accordance with ASTM D3759 (column 1 lines 48-63). At the time of the invention, it would have been an obvious to one skilled in art to modify the device of Burgess, Holden and Desnoyers to include the adhesives of the tensile load (lb/in-width) approximately equivalent to 25 pounds/inch in accordance with ASTM D3759, as taught by Huddleston et al. to have more resiliencies to the device.

Response to Amendment

13. The declaration under 37 CFR 1.132 filed 12/3/08 is insufficient to overcome the rejection of claims 44-80 based upon Burgess, Holden, Domenico, Desnoyers and Huddleston et al. as set forth in the last Office action because: the affidavit of Dr. David M. de Lemos filed on 12/3/08 does not provide enough evidence to support the

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applicant's argument and overcome art of record. The example of David's wife study is a single example, not the studies of multiple patients which have been conducted and provided statistical data to support for applicant claimed invention and to overcome the art of record. Further, Dr. de Lemos give his opinion about the background of Plantar fasciitis and applicant invention, to that the examiner respectfully point out that these arguments are only Dr. de Lemos opinion in his word without fact base evidence to support the claimed invention and to overcome the art of record. Dr. de Lemos again discussed that the Mr. Bushby's product provides a solution to the long-standing problem, to this statement the examiner is not clear which long-standing problem Dr. de Lemos is referring to. Further, to establish a long felt need applicant is required to provide evidence that shows there is a long felt need and where this evidence also support the claimed invention provides a result to this long felt need to overcome the art of record has not been met.

Response to Arguments

14. Applicant's arguments filed 7/9/09 have been fully considered but they are not persuasive.

15. With respect to applicant's argument that the device of Burgess is simply a cushioning device to protect the sole of the foot, it is not an orthotic device, to these argument the examiner would like to point out that the applicant is claiming orthotic foot support comprising as claimed in preamble of claim and claim reciting comprising is open ended claim and has been broadly interpreted to provide the structure required by the rest of claim of limitations. Further, the claim as recited does not claim any distinct

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structure to preclude the foot protector of Burgess to meet the claim limitations as claimed or to define an orthotic as claimed in preamble. The recitation orthotic has not been given patentable weight because it has been held that a preamble is denied the effect of a limitation where the claim is drawn to a structure and the portion of the claim following the preamble is a self-contained description of the structure not depending for completeness upon the introductory clause. *Kropa v. Robie*, 88 USPQ 478 (CCPA 1951).

16. With respect to applicant's argument to size and shape that the Burgess specifically states that its foot protector can only be slightly smaller than the sole of the foot, unlike the applicant's claimed invention. To these arguments the examiner respectfully would like to point out that the applicant's claim require to cover only a portion of the wearer's sole, at least a portion of sole, to that the examiner's interpretation is that the at least a portion includes the whole foot and to cover only a portion could meet by the Burgess's device because slightly smaller is a portion which is uncovered as required by the claim and would still protect some of foot.

17. With respect to applicant's argument that the evidence is not considered, please refer above to response to amendment.

18. With respect to applicant's argument that the evidence A-D as submitted on 12/4/08 and declaration, please refer above to response to amendment. Further, the claims are not directed to treat plantar fasciitis, further, all the evidence A-D provide information about preventing plantar fasciitis by exercise and stretches, arch support in shoe, inserts and night splints, further discloses that these modalities alone will cure the

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plantar fasciitis pain in most patients. Therefore, these evidences do not provide additional evidence or support to applicant argument and overcome the art of record Burgess to the claimed invention. Further, as disclosed in Exhibit B that toe exercises can increase the strength and resiliency of the plantar fascia. In view of the foregoing, when all of the evidence is considered, the totality of the rebuttal evidence of nonobviousness fails to outweigh the evidence of obviousness.

With respect to applicant's argument directed to the stretch resistance, please see rejection above. Applicant sets forth in the disclosure of the invention that "the stretch resistant device" is a sufficiently flexible article with adhesive lining and that has an adhesive on the sole of the lining and that when the lining is adhered to the surface of a foot, the lining imparts at least some restriction to extension and stretching of the tissue. Similarly, the liner of Burgess, when applied to the sole of a foot, is applied via an adhesive on the liner and it is obvious that applying a liner with an adhesive, such as the Burgess device, to the bottom of the foot will provide some degree of restriction to the skin thus providing a means of prevention or restriction of extension and stretching of the tissue. Therefore, Burgess's liner is equivalent to the claimed support's "stretch resistant" property, since there are no other distinguishing structural elements that are claimed to provide this restriction of extension and stretching of the tissue. Further, it is again pointed out that this claim limitation of "stretch resistance" only requires the liner provide some degree of resistance to extension and stretching, and it is the position of the examiner that the device of Burgess meets this claimed limitation.

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Also, applicant's own specification discloses his invention with the implication that it is only necessary to apply an adhesive to the sole of the foot to have some treating effect (see page 20 of applicant's original disclosure). The specification further teaches that additionally including straps and then connecting the straps is taught to be only an additional support.

Further, applicant does not disclose any specific type, amount, or degree of adhesive to have a therapeutic effect. If anything is adhered to the sole of a foot with it will impose some restriction of free motion of the sole of the foot and restrict some degree of stretching of the sole of the foot. Additionally, Burgess discloses that the adhesive can effectively bond the liner to the foot such that it is less likely to fall off during normal activities (see column 4, lines 20-27 of applicant's original disclosure). Furthermore, Burgess discloses that their device conforms to the shape and contours of the sole of the foot and adjusts to flexing of the sole of the foot during walking or running without the adhesive tearing away from the foot (column 3 lines 40-51).

Lastly, no evidence has been provided by applicant to show that the adhesive layer of Burgess could not perform the restriction and resistance to stretching. It is the burden of applicant to provide convincing evidence against a prima facie case set forth by the examiner.

19. With respect to applicant's argument to woven micro-fiber, please refer to corresponding claims rejection.

20. With respect to argument's to address the limitation of not using a resilient cushion layer, please refer to corresponding claim rejection.

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With respect to applicant's argument to thickness of the applicant's invention as opposed to the prior art, the examiner respectfully would like to point that a change in size is generally recognized as being within the level of ordinary skill in the art. *In re Rose*, 105 USPQ 237 (CCPA 1955).

21. With respect to applicant's arguments to the limitations of the strength of adhesiveness of the applicant as opposed to the prior art, to these arguments the examiner respectfully disagrees. Further, applicant does not disclose any specific type, amount, or degree of adhesive to have a therapeutic effect. If anything is adhered to the sole of a foot with it will impose some restriction of free motion of the sole of the foot and restrict some degree of stretching of the sole of the foot. Additionally, Burgess discloses that the adhesive can effectively bond the liner to the foot such that it is less likely to fall off during normal activities (see column 4, lines 20-27 of applicant's original disclosure). Furthermore, Burgess discloses that their device conforms to the shape and contours of the sole of the foot and adjusts to flexing of the sole of the foot during walking or running without the adhesive tearing away from the foot (column 3 lines 40-51).

Further, there is no evidence has been provided by applicant to show that the adhesive layer of Burgess could not perform the restriction and resistance to stretching. It is the burden of applicant to provide convincing evidence against a prima facie case set forth by the examiner.

22. With respect to argument to ratio of elongation please refer to 112 rejection above, and further the examiner would like to point that how applicant is determined the

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ratio of elongation of less than 0.9, whether is it linear ratio? Was is determine up to tear or breaking point of material? How is it determined? There is no substantially data or examples to support the finding of these specific claim limitations. Further, one having ordinary skill in art if use lesser pound weight to tensile strength of Desnoyers's article would provide lesser ration of elongation, therefore, Desnoyers meets the claim limitation, since there is not enough disclosure for one having ordinary skill in art to know how applicant eventually determine the claim limitation. Further, if 0.01 pound weight is used to determine the ration of elongation in Desnoyers device would eventually determine the ration as required by the claim.

23. With respect to the critical limitation of an orthotic device having less than 15% elongation when subjected to a 25 lb tensile load, the examiner would like to refer to the response to argument for orthotic versus foot protector above. Further, Huddleston reference is used for its adhesive (please see rejection above) not for device as whole.

Conclusion

Any inquiry concerning this communication or earlier communications from the examiner should be directed to TARLA R. PATEL whose telephone number is (571)272-3143. The examiner can normally be reached on M-T 6-3.30.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Patricia Bianco can be reached on 571-272-4940. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

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/Tarla R Patel/
Examiner, Art Unit 3772

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